URGENT FIELD SAFETY NOTICE (FSN) / PRODUCTS RECALL

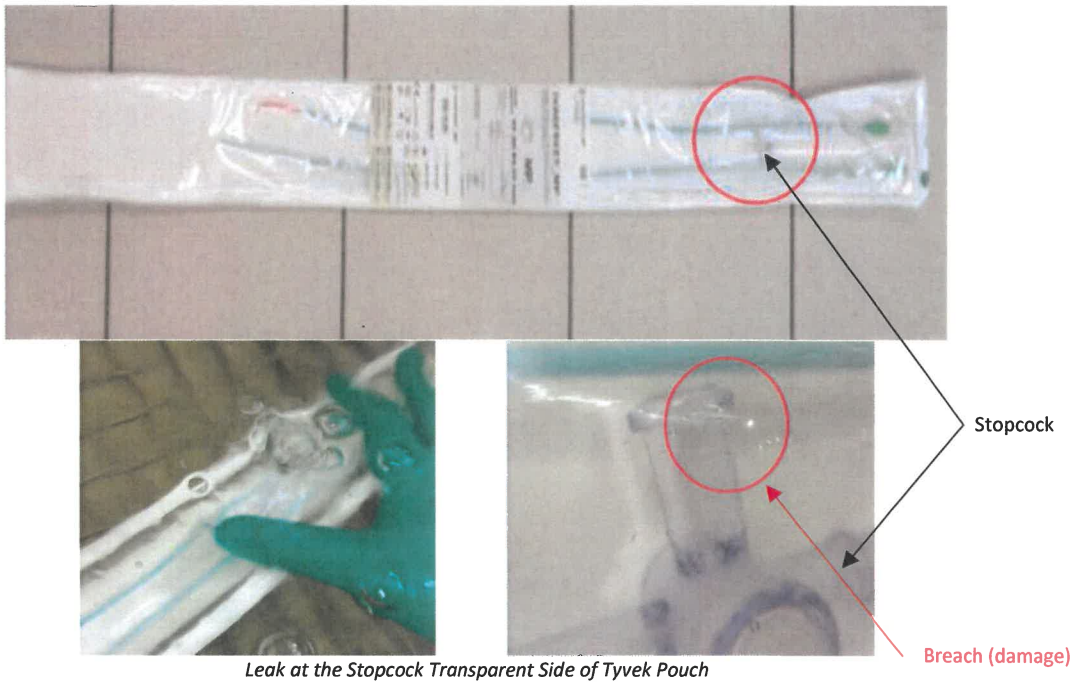
Issue Date: 13 OCTOBER 2021

FSN #: 20211013_IVA Long Sterile Barrier Breach
PURPOSE: Sterile barrier breach on the IVA sterile packaging
PRODUCT RANGE (INTENDED USE): IVA (multipurpose introducer sheath)
PRODUCT REF: *IVA3F50, IVA5F45, IVA5F41.45, IVA5F96.45, IVA6F80, EIVA6F80, IVA6F80ST, EIVA6F80ST, IVA6F80ST_MP, EIVA6F80ST_MP, IVA7F41.45, IVA7F96.45 and IVA7F96.90*
LOTS #: All lot numbers with manufacturing date greater or equal to **2016-10** 2016-10 and less or equal to **2021-09** 2021-09

Who may be affected: Distributors, Safety Officers, Pharmacists, Vigilance Coordinators, and Head of Neuroradiology Department in Healthcare Centers.

Dear Partners,

During the 5 years stability study for the IVA Long products, bubble leak testing was performed; Balt Extrusion SAS identified a leak on the pouch near where the stopcock contacts the Tyvek transparent side of the pouch (see below picture for illustration).



Leak at the Stopcock Transparent Side of Tyvek Pouch

The Hazard of being exposed to non-sterile products may arise when the following hazardous situation occurs; a physician uses an IVA Long Introducer Sheath with a breached sterile barrier on a patient. The perforated pouch may lead to a risk of the device producing infection or microbiological contamination. The pouch damage is not likely detectable before the clinical use of the device as the damage on the pouch may not be visible with the unaided eye.

The preliminary investigation revealed that the cause of pouch damage is related to packaging design. Specifically, the combination of the size of the pouch, the shelf box, and the unconstrained stopcock within the packaging.

Balt has not received any customer complaints for the IVA long product related to sterile barrier breach; However, to prevent any issue during the use of IVA Long devices with patients, BALT Extrusion SAS has decided to recall from the market all long IVA products, manufactured from October 2016 (2016-10) to September 2021 (2021-09) included.

BALT EXTRUSION SAS
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F: +33 (0)1 34 17 03 46
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95160 Montmorency • France
www.balt.fr

Procedure to be applied by distributors/ subsidiaries:

- For outside EEA, inform your customers and your local competent authority about this notice;
- For inside EEA, inform your customers about this notice;
- Identify and locate the IVA Long products concerned by this recall procedure;
- Collect and put in quarantine the IVA Long products concerned by this recall procedure and then return them to BALT Extrusion SAS through the usual "RMA" (Return Material Authorization) procedure by contacting our customer service;
- Keep informed BALT Extrusion SAS about the status of every unit of IVA Long product concerned by this recall procedure;
- Fulfill the "Notice of receipt" (cf. annex) then return it to BALT Extrusion SAS via the indicated contact;
- Contact BALT Extrusion SAS for any additional information.

Procedure to be applied by the hospital staff:

- Inform, within your hospital, Safety Officers, Pharmacists, Vigilance Coordinators, Head of Neuroradiology and the neuroradiology department staff, as well as any other person if deemed necessary;
- Identify and locate the IVA Long products concerned by this recall procedure;
- Collect and put in quarantine the IVA Long products concerned by this recall procedure and then return them to your local distributor as per its return procedure;
- Keep informed your local distributor or BALT Extrusion SAS about the status of every unit of IVA Long product concerned by this recall procedure;
- Contact your local distributor or BALT Extrusion SAS for any additional information.

Should you require any additional information about this Field Safety Notice (FSN), do not hesitate to contact our Quality Department or your local distributor.

Contact:
Quality Department
✉ : claim@baltgroup.com
BALT EXTRUSION SAS
10 RUE DE LA CROIX VIGNERON 95160 MONTMORENCY - France
☎: +33.1.39.89.46.41 / Fax: +33.1.34.17.03.46

We apologize for any inconvenience that this action may cause, and we thank you for your cooperation.

Paul Ruthenbeck-Chiaramonte
Quality Director
Vigilance Coordinator Deputy

13OCT2021

Annex: Notice of Receipt ref. # 20211013_IVA Long Sterile Barrier Breach

RETURN THE COMPLETED RECEIPT BY: FAX: +33.1.34.17.03.46 / MAIL: BALT EXTRUSION 10 RUE DE LA CROIX VIGNERON 95160 MONTMORENCY (Quality Department) / **E-MAIL:** claim@baltgroup.com

We hereby acknowledge the receipt of the field safety notice reference "20211013_IVA Long Sterile Barrier Breach" and we undertake to implement the actions therein mentioned.

NAME:	
TITLE:	
COMPANY/ HOSPITAL:	
LOCATION:	
CONTACT (E-MAIL AND/OR PHONE):	
DATE:	
SIGNATURE:	

☐ We confirm that, after verification of our stock and the stocks of our users, we declare having no IVA Long products (with manufacturing date from 2016-10 to 2021-09) concerned by this recall procedure.

☐ If not, please, indicate the volume of IVA Long product(s) (with manufacturing date from 2016-10 to 2021-09) by reference concerned by this recall procedure:

Product reference	Quantity to be returned to BALT Extrusion SAS	Product reference	Quantity to be returned to BALT Extrusion SAS
IVA3F50		**EIVA6F80ST**	
IVA5F45		**IVA6F80ST_MP**	
IVA5F41.45		**EIVA6F80ST_MP**	
IVA5F96.45		**IVA7F41.45**	
IVA6F80		**IVA7F96.45**	
EIVA6F80		**IVA7F96.90**	
IVA6F80ST			

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